UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,993	02/17/2004	James D. Lewis JR.	HT-5755 DIV	1329

29200 7590 09/19/2008

BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DF2-2E
DEERFIELD, IL 60015

EXAMINER	
MOHANDESI, JILA M	
ART UNIT	PAPER NUMBER
3728	

MAIL DATE	DELIVERY MODE
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAMES D. LEWIS, JR., WILLIAM BACCIA, JOSEF SCHMIDT, JOHAN VANDERSANDE, JOHN CARL CARD, THEODOR LANGER, GEORG HABISON, HELMUT EDER

Appellants

Appeal 2008-4787
Application 10/779,993
Technology Center 3700

Decided: September 19, 2008

Before RICHARD TORCZON, SALLY GARDNER LANE, and JAMES T. MOORE *Administrative Patent Judges*.

LANE, *Administrative Patent Judge*.

DECISION ON APPEAL

I. STATEMENT OF THE CASE

The appeal is from a Final Rejection of claims 1-12, 22, 25, 26, and 28-33. 35 U.S.C. § 134. Claims 13-21, 23, 24, and 27 have been canceled,

and claims 34-36 have been withdrawn. (App. Br. 4). We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

The application was filed February 17, 2004. It was published on August 19, 2004, as Application Publication 2004/0159974. The real parties in interest are said to be Baxter International, Inc. and Baxter Healthcare S.A. (App. Br. 2).

The Examiner relied on the following references:

Name	Number	Date
Johnston	4,692,361	Sep. 8, 1987
Bacehowski	4,910,147	Mar. 20, 1990
Bell	4,936,456	Jun. 26, 1990

The Examiner rejected claims 1-7, 11, 12, 22, 25, and 28-33 under 35 U.S.C. § 103(a) over Johnston. For this rejection, the Appellants argue separately for the patentability of claims 1 and 30.

The Examiner also rejected claims 8 and 16 under 35 U.S.C. § 103(a) over the combination of Johnston and Bacehowski. The Appellants also appeal this rejection and argue these claims as a single group.

Finally, the Examiner rejected claims 9 and 10 under 35 U.S.C. § 103(a) over the combination of Johnston and Bell. The Appellants also appeal this rejection and argue these claims as a single group.

II. FINDINGS OF FACT

The record supports the following findings of fact as well as any other findings of fact set forth in this opinion, by at least a preponderance of the evidence.

1. Appellants' claim 1 recites:

> A container for holding albumin comprising:
> a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold, and permanent seals about a periphery of the first and second walls;
> an albumin concentration of at least about 20% in the cavity;
> a seal area free of the albumin concentration;
> a permanent heat seal formed on the seal area, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container, wherein the albumin concentration of at least about 20% contacts the interior portion and is stored within the fluid-tight chamber.

(App. Br., Claims Appx. i).

2. Appellants' claim 30 recites:

> A container for holding albumin comprising:
> a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold, and permanent seals about a portion of a periphery of the first and second walls;
> a seal area forming an opening to the cavity; and
> an albumin concentration added through the opening so that the seal area is free of albumin concentration.

(App. Br., Claims Appx. iv).

3. Johnston relates to "[f]lexible containers [that] are utilized in the medical industry for containing, inter alia, parenteral solutions, dialysis solutions, frozen drugs, nutrition products, respiratory therapy products, and plasma." (Johnston col. 1, ll. 11-14).

4. Figure 2 of Johnston is reproduced below.

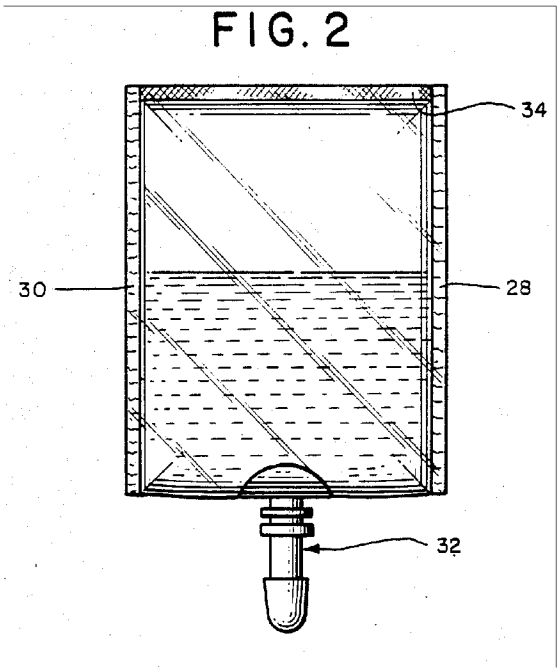

Figure 2 depicts a "flexible container **26**[1] constructed from the film laminate **10** of this invention . . . . As illustrated, the inside layer **24** [of the laminate **10**] is heat sealed together on itself to create walls **28, 30** and **34**. Due to the construction of the inside layer **24**, a strong heat seal is created." (Johnston col. 6, ll. 51-56).

5. Johnston teaches that "[i]n order to create a flexible container **26** the inside layer **24** must be sealed to itself on at least two walls **28** and **30**." (Johnston col. 4, ll. 25-27).

6. Appellants' claim 8 recites:

> The container of claim 3[2], further comprising an aperture adjacent an edge opposing the fitment.

---

[1] Element 26 is not labeled in the figures of Johnston, but it is assumed to be the whole device depicted in Figure 2.

[2] As recited in Appellants' Claims Appendix, claim 8 depends from claim 3, which depends from claim 1. Claim 8 references "the fitment," but neither

(App. Br., Claims Appx. ii).

7. Appellants' claim 3 recites:

> The container of claim 1, wherein the bag has a plurality of peripheral edges that are sealed, and another peripheral edge that contains the fold.

(App. Br., Claims Appx. i).

8. Johnston teaches "a fitment **32** may be sealed to the outside layer **12** of the container **26**. Preferably, the fitment **32** is heat sealed to the outside layer **12**. Due to the construction of the outside layer **12**, a strong heat seal is created." (Johnston col. 6, ll. 57-61).

9. Johnston does not specifically disclose "an aperture adjacent an edge opposing the fitment."

10. Bacehowski relates to flexible containers for "containing cell culture media and other sensitive fluids." (Bacehowski col. 1., ll. 6-9).

11. Figure 1 of Bacehowski is reproduced below.

---

claim 1 nor claim 3 recites "a fitment." Thus, claim 8 is an improper dependent claim for lack of antecedent basis.

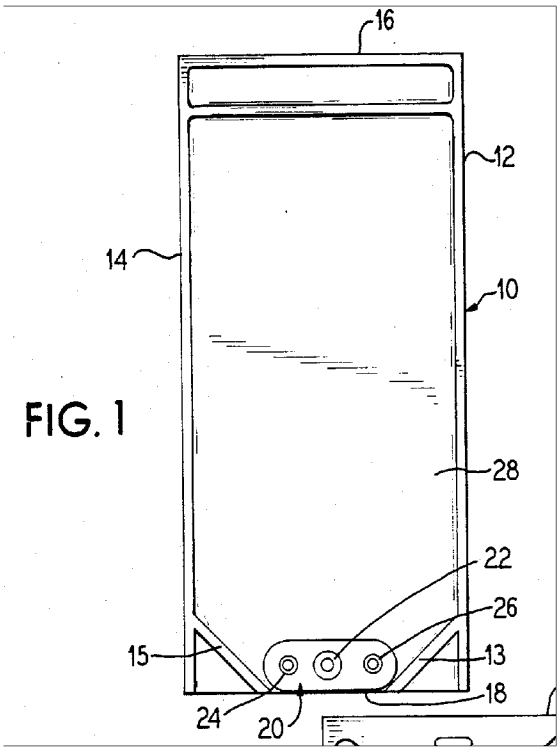

FIG. 1

Figure 1 depicts a "container **10**[, which] includes a fitment **20**." (Bacehowski col. 5, ll. 6-7).

12. The fitment **20** of the container disclosed in Bacehowski is adjacent an edge that opposes the aperture depicted parallel to edge 16.

13. Appellants' claim 9 recites:

> The container of claim 3, further comprising at least one chevron seal in the fold.

(App. Br., Claims Appx. ii).

14. Johnston does not specifically disclose a chevron seal in the fold.

15. Bacehowski teaches "[i]n an embodiment of the container **10** illustrated, the container includes chevron seals **13** and **15**. The chevron seals **13** and **15** improve the delivery characteristics of the container **10**." (Bacehowski col. 4, ll. 10-13).

16. Bell relates to bags that can be sterilized. (Bell col. 1, ll. 8-11).

17. Bell provides an embodiment wherein an end of the bag is "closed by means of a chevron seal . . . . As a result of the chevron construction, relatively long tabs . . . are formed in areas . . . to facilitate opening through stripping of the gussets . .. from the bag . . . ." (Bell col. 9, ll. 27-35).

18. Bell provides for "[a] variety of edge seam arrangements seal or seam types . . .," including "heat seals," adhesive seals" and "peelable seals." (Bell col. 5, ll.

III. LEGAL PRINCIPLES

The Supreme Court has noted that "when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR Int'l v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007). Furthermore, "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.*

"[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject

matter shown to be in the prior art does not possess the characteristic relied on." *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971); *see also In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) ("Under the principles of inherency, if a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim of an application, the claim is anticipated.").

IV. ANALYSIS

Claims 1-7, 11, 12, 22, 25, and 28-33

We review claims 1 and 30 as a representative claims for this rejection. 37 C.F.R. § 41.37(c)(1)(vii).

Appellants claim 1 recites a container for holding albumin comprising "an albumin concentration of at least about 20% in the cavity" of the container. (FF[3] 1). Appellants argued that "*Johnston* fails to disclose or suggest a flexible container containing an albumin concentration of 20% as required by Claim 1. . . . In fact, *Johnston* fails to even disclose or suggest albumin in a container anywhere in his disclosure." (App. Br. 12). Appellants argued further that "because albumin operates as an insulator, the presence of a high albumin concentration on the seal area before heat sealing would be expected to result in a compromised or weakened heat seal, which makes it difficult to manufacture heat sealed containers containing albumin." (App. Br. 13).

Although Johnston does not expressly teach that the container it discloses would hold albumin of a concentration of 20%, Johnston does

---

[3] Finding of Fact.

disclose that the container would hold plasma. (FF 3). Plasma contains albumin. Thus, Johnston teaches a container for holding albumin. One skilled in the art would have had a reason to use the container of Johnston with any concentration of albumin since doing so have been no more than using a known product for its known use.

According to Appellants,

> [i]n addition to approximately 4% albumin, human plasma contains hundreds of other components including, for example, clotting factors VIII and IX, immunoglobulins, transport proteins such as haptoglobin and transferrin, and enzyme inhibitors. Consequently, plasma exhibits properties quite different from a 20% albumin solution as recited in the claims, which result in very different packaging requirements. In particular, concentrated albumin solutions are highly susceptible to denaturation when exposed to heat, making such solutions difficult to sterilize and challenging to package in heat-sealable plastic containers such as that of *Johnston.*

(Reply Br. 3-4). Appellants did not provide probative evidence in support of their argument that "approximately 4% albumin" has "very different packaging requirements" than the claimed "at least about 20%" albumin. *See Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA 1977) ("Argument of counsel cannot take the place of evidence lacking in the record."). Nor do we do we find any teaching in Appellants' specification that an albumin concentration of "at least about 20%" is significantly different from other albumin concentrations for packaging requirements. Appellants have not directed us to any persuasive evidence why those of skill in the art would not have a reasonable expectation of success in using the container of Johnston with "at least about 20% albumin." Thus, we conclude that it would have been obvious to one skilled in the art to use "at least about 20%," albumin as

claimed, in the container taught by Johnston, *see KSR, supra* and are not convinced by Appellants' arguments that Johnston does not present a prima facie case for obviousness.

Appellants also argued that Johnston

> fails to disclose or suggest that the container has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration as required by Claim 1. In addition, *Johnston* fails to disclose or suggest an albumin concentration is added through the opening so that the seal area is free of albumin concentration as required by Claim 30.

(App. Br. 12). As explained above, the description of Johnston encompasses a container that includes "a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold, and permanent seals about (a portion of) a periphery of the first and second walls," as claimed in claims 1 and 30. The Examiner asserted that

> the seal area where the fitment/fill tube is heat sealed to the outside layer of the flexible bag the seal area will be free of albumin concentration (since this heat seal is formed prior to filling the flexible bag with albumin) and a permanent heat seal is formed around the fitment/fill tub area, see column 6, lines 57-61 and Figure 2 embodiment.

(Ans. 5). The Examiner set forth a reasonable basis for finding the Johnston inherently discloses a container that has a "seal area free of the albumin concentration," as claimed. Appellants have not provided probative evidence sufficient to show that the seal described in Johnson would not be free of albumin concentration. *See Swinehart, supra; Meitzner, supra*.

Appellants argued further that "*Johnston* has no disclosure whatsoever with respect to: . . . 2) a container with a seal area free of the albumin

concentration before heat seal formation" (App. Br. 12), and that "*Johnston* provides no processes or techniques to successfully fill his container with an albumin concentration and then seal the container while avoiding the problems of albumin degradation and albumin interference at the seal area." (Reply Br. 3). Neither claim 1 or 30 includes terms that limit the container to filling before making the heat seals. In addition, claims 1 and 30 recite containers "comprising" the recited elements, which allows for other filling means for the containers. Thus, we do not find these arguments convincing.

Finally, Appellants argued that

> not only does *Johnston* fail to disclose or suggest every element of the present claims, *Johnston* fails to even recognize the advantages, benefits and/or properties of a heat sealed container holding albumin in accordance with the present claims. Accordingly, the novel and non-obvious processes of the present specification (see related U.S. Patent No. 6,718,735) produce the claimed containers of albumin that are novel and non-obvious as well.

(App. Br. 13; *see also* Reply Br. 4). That a patent was issued on a process disclosed in Appellants' specification does not by that fact alone assure the patentability of a product disclosed in the same specification. *See In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) ("The patentability of a product does not depend on its method of production. [citation omitted] If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.").

Accordingly, we are not convinced that the Examiner erred in rejecting claims 1 and 30 under 35 U.S.C. § 103(a) over Johnston.

Claims 8 and 26

We review claim 8 as a representative claim for this rejection. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 8 recites a container as in claim 1, wherein the bag has a plurality of peripheral sealed edges and a fold and "further comprising an aperture adjacent an edge opposing the fitment." (FFs 6 and 7). The Examiner asserted that those in the art would have used the positioning of the aperture in Bacehowski (FFs 11 and 12) "to facilitate hanging of the flexible bag." (Ans. 5). Appellants did not dispute this reason to combine Johnston and Bacehowski or any other aspect of the prima facie case for obviousness of claim 8 beyond that of claim 1, but argued that "[e]ven with *Bacehoweksi* as an additional reference the cited art fails to teach or suggest the elements of Claims 8 and 26 in combination with the novel elements of Claim 1. . . . *Bacehowski* has no disclosure whatsoever directed to a flexible container that contains an albumin concentration or even the term 'albumin'" (App. Br. 14). Appellants also did not provide any arguments or evidence to rebut the prima facie case of claim 8.

Accordingly, the Examiner did not err in rejecting claim 8 over 35 U.S.C. § 103, over Johnston and Bacehowski.

Claims 9 and 10

We review claim 9 as a representative claim for this rejection. 37 C.F.R. § 41.37(c)(1)(vii). Claim 9 recites:

> The container of claim 3, further comprising at least one chevron seal in the fold.

(FF 14). Johnston does not specifically disclose a chevron seal in the fold. (FF 15). Bell relates to bags that can be sterilized (FF 17) and are "closed by

means of a chevron seal . . . . to facilitate opening through stripping of the gussets . . . (FF 18), a structure in the bags disclosed in Bell.

Appellants argued that

> *Bell* teaches away from the flexible container having permanent peripheral seals as recited in the present claims. For example, Bell discloses a flexible bag made with peripheral peel seals, which teaches away from a container having permanent seals in accordance with the present claims. See, *Bell*, column 5, line 60 to column 6, line 16 and Figure 1.

(App. Br. 15). Appellants did not argue that the chevron seals taught in Bell would have been inoperable in the container disclosed in Johnston or that those of skill in the art would not have had reason to combine them given the disclosures of the references. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F3d 551, 553 (Fed. Cir. 1994). Bell teaches peelable seals as one of a "variety of edge seam arrangement seal or seam types . . . " (FF 19), but does not discourage the use of permanent seals. Appellants did not provide any evidence to rebut the prima facie case created by the combination of references or the use of chevron seals. Accordingly, the Examiner did not err in rejecting claim 9 over 35 U.S.C. § 103(a), over Johnston and Bell.[4]

---

[4] We note that Bacehowski teaches "chevron seals [that] improve the delivery characteristics of the container . . . ." (FF 16). Thus, the combination of Johnston and Bacehowski also presents a prima facie case for the obviousness of claim 9.

V. ORDER

Upon consideration of the record and for the reasons given,

the Examiner's rejection of claims 1-7, 11, 12, 22, 25, and 28-33 under 35 U.S.C. § 103(a) over Johnston is AFFIRMED;

the Examiner's rejection of claims 8 and 26 under 35 U.S.C. § 103(a) over Johnston and Bacehowski is AFFIRMED; and

the Examiner's rejection of claims 9 and 10 under 35 U.S.C. § 103(a) over Johnston and Bell is AFFIRMED.

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

MAT

Baxter Healthcare Corp.
1 Baxter Parkway
DF2-2E
Deerfield, IL 60015